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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,133	10/27/2000	Masayuki Hara	07898-061001	6449

7590 12/17/2002

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/699133	Hara et al
Examiner <i>Xiaofan</i> Han	Group Art Unit 1451

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 4/23/02

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

Claim(s) 5, 6 + 8-28 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 5, 6 + 8-28 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). 3 *filed 10/12/01*

Notice of Reference(s) Cited, PTO-892

Notice of Draftsperson's Patent Drawing Review, PTO-948

Interview Summary, PTO-413

Notice of Informal Patent Application, PTO-152

Other _____

Office Action Summary

In a response of 4/23/02 to a restriction requirement of 3/27/02, applicants elected Group I claims 5 and 6, canceled claims 1-4 and 7 drawn to the nonelected invention, and added new claims 8-27.

5 The newly added claims contained two claims number 22. Therefore, starting with the second claim 22, the claims have been renumber 23-28.

Claims examined on the merits are 5, 6 and 8-28 which are all claims in the application.

Claim Rejections - 35 USC § 112

10 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15 Claims 6 and 8-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 1 of claim 6, "piling up a cell" and in line 6 of the claim "piling----cell layer on another cell" is confusing since the specification discloses placing one layer on another layer, and not placing one cell on another cell or placing a cell layer on a cell. It is suggested that "piling up a cell" in line 1 be replaced with -- forming a structure having multiple cell layers --. In line 6, the claim is further confusing as to how the cell is formed on the carrier to which the cell layer is applied. In view of the specification, it appears the cell formed on the carrier is a cell layer formed in the same way as the cell layer exfoliated. It is suggested that line 6 be amended to recite

-- placing the exfoliated cell layer on another cell layer formed on the carrier as required by step (a) --. This type of change should also be made to step (c) of claim 26. Additionally, in line 5 of claim 26, "an" and in line 6 of the claim "a" should be changed to -- the -- to be

5 clear.

Claims 18-20 are confusing by reciting a specific thickness as an alternative to a range. The specific thickness should be in a separate dependent claim. Claim 19 is confusing by not stating that thickness has the dimensions required.

10 Claims 27 and 28 are confusing by not requiring a step of obtaining the result required by the preamble of the claims, i.e. claim 27 should require a step that forms a three-dimensional structure and claim 28 should require a step of drug testing. Additionally, the term "drug permeability testing" is uncertain as to meaning and scope.

15 **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

20 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to

30 point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 8-25, 27 and 28 are rejected under 35 U.S.C. 103(a) as 5 being unpatentable over Hanley Jr et al (6,080,579) in view of Shah (5,976,780).

The claims are drawn to culturing cells on an alginate layer on a porous membrane.

Hanley Jr et al disclose culturing cells on an alginate layer (col 10 5, lines 19-25).

Shah discloses using a porous membrane having an alginate layer when culturing cells (claim 17).

It would have been obvious to provide the alginate layer of Hanley Jr et al on a porous membrane as suggested by Shah for the expected 15 function of the membrane in combination with the alginate layer as suggested by Shah. An alginate layer on a membrane is a three-dimensional structure, and testing in claim 28 would have been an obvious use of culturing cells.

Claims 6 and 26 are free of the prior art.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number 5 (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist 10 whose telephone number is (703) 308-0196.

15 DMN
12/16/02



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651